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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE SERIAL NUMBER Ď 90028574 State FAUSTMAN 09/09/92 887925.627 EXAMINER HM22/0912 PAPER NUMBER ART UNIT PAUL T. CLARK CLARK & ELBING LLP 176 FEDERAL STREET 1648 BOSTON MA 02110-2214 09/12/00 DATE MAILED: This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS 11 19 99 This action is made final. Responsive to communication filed on_ his application has been examined days from the date of this letter. _month(s), _ A shortened statutory period for response to this action is set to expire Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 2. Notice of Draftsman's Patent Drawing Review, PTO-948. 1. Notice of References Cited by Examiner, PTO-892. 4. Notice of informal Patent Application, PTO-152. Notice of Art Cited by Applicant, PTO-1449. 5. Information on How to Effect Drawing Changes, PTO-1474... Part II SUMMARY OF ACTION are pending in the application. 1. Ciaims_ ____ are withdrawn from consideration. Of the above, claims have been cancelled. 2. Claims 39-44, 47, 57, 59 € 60 __ are objected to. 5. Claims _ are subject to restriction or election requirement. 6. Claims_ 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. . Under 37 C.F.R. 1.84 these drawings 9. The corrected or substitute drawings have been received on ____ are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on ______ has (have) been approved by the examiner; \Box disapproved by the examiner (see explanation). ___, has been approved; disapproved (see expianation). 11. The proposed drawing correction, filed ____ 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received □ been filed in parent application, serial no. ______; filed on ______; 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

EXAMINEDIO.

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Claims 36-97 should be pending in this application. However, the amendment adding claims 89-91 is missing from the examiner's file. Claims 36, 39-44, 47, 57, 59 and 60 are considered, in keeping with applicant's election, below.

Claims 36, 39-44, 47, 57, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for F(ab')2 fragments, does not reasonably provide enablement for other masking agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification clearly fails to teach a transplantable composition for use in humans comprising a cell or tissue of a type normally bearing a surface antigen that causes an immune response against the cell or tissue in a human recipient wherein the antigen is modified, masked, or has been partially or wholly eliminated to decrease said immune response, such that upon introduction of the composition into a human, lysis of said cell or tissue is prevented commensurate in scope with that which is claimed. That is, the specification merely offers, as examples, a couple of F(ab')2 fragments as masking agents. Again, no other masking agent such as an intact antibody, receptor, ligand, etc. has been exemplified in the specification. However, the claims clearly encompass such agents while lacking enablement for such breadth. The claims should be properly limited to that which is taught in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

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Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

Laurie Scheiner/LAS September 7, 2000

> LAURIE SCHEINER PRIMARY EXAMINER